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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/424,059 | 11/18/99 | NUNOKAWA | Y 001560-376 |

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| EXAMINER | |
|---|---|
| JAYARAM, B | |
| **ART UNIT** | **PAPER NUMBER** |
| 1624 | 4 |

**DATE MAILED:** 05/02/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/424,059 | NUNOKAWA ET AL. | |
| | Examiner | Art Unit | |
| | Beby Jayaram | 1624 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

14) ☒ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other: .

## DETAILED ACTION

Claims 1-37 are pending in this application.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Scope of "optionally substituted " groups is not adequately enabled. No explanation has been provided for the size or nature of these groups. Scope of the "optionally substituted" in the claims read on all functional moieties regardless of complexity of structure, rings having any number of nitrogen, oxygen, sulfur atoms in any array for heteroaryl/heterocyclic. In view of the lack of direction provided in the specification regarding starting materials, lack of working examples, and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to make the claimed compounds and therefore to practice the invention.

Claims 11-14 and 29 drawn to prevent various diseases. The scope of the compound claim is not adequately enabled solely based on the compound's effect on

preventing various diseases. Instant claim language embraces infections not only for treatment but also for PREVENTION which is not remotely enabled. While treatment of certain known diseases has been linked with the use of compounds similar to these, the art does not recognize use of such inhibitors as broad based drugs for treating all disorders instantly embraced, both present and future.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-37 are rejected under 35 U.S.C.112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

In claim 1 the word "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements. See MPEP 2111.03.

Claim 16 is a substantial duplicate of claim 1.

Claim 29 is a substantial duplicate of claim 16.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nunokawa et al., EP 0864648. The reference teaches a generic group of compounds which embraces applicants' instantly claimed compounds. See formula in page 5. The compounds are taught to be useful in regulating the expression of human-induciable nitric oxide synthase. The claims differ from the reference by reciting a specific species and/or a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as whole i.e., as therapeutic agents. One of the ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. *In re Susi*, 440 F.2nd 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal *Circuit in Merck & Co. v. Biocraft Laboratories*, 847 F.2nd 804, 10USPQ 2nd 1843, 1846 (Fed. Cir. 1989).

Claims 1-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al., Chem. Pharm. Bull, 41(1) 139-144. The reference teaches a generic group of compounds which embraces applicants' instantly claimed compounds. See formula in fig 1 on page 139. The compounds are taught to be useful as inhibitors of

platelet aggregation. The claims differ from the reference by reciting a specific species and/or a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as whole i.e., as therapeutic agents. One of the ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Beby Jayaram, whose telephone number is (703) 308-7023. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

The fax number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Mukund J. Shah

bj

**Mukund J. Shah**
**Supervisory Patent Examiner**
**Art Unit 1624**